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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,414	06/30/2003	David P. Holden	ABIOS.021A	1954
22896 7590 11/16/2007 MILA KASAN, PATENT DEPT. APPLIED BIOSYSTEMS 850 LINCOLN CENTRE DRIVE FOSTER CITY, CA 94404			EXAMINER SIMS, JASON M	
			ART UNIT 1631	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/611,414

Applicant(s)

HOLDEN ET AL.

Examiner

Jason M. Sims

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-85 is/are pending in the application.
- 4a) Of the above claim(s) 22-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19, 20, 21, 84, and 85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/2007 has been entered.

Claims 22-83 remain withdrawn as being drawn to a non-elected inventive group.

Claims 1-17, 19-21, and 84-85 are the current claims hereby under examination.

Claim Rejections - 35 USC § 101

The following rejection is being maintained:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-17, 19-21, and 84-85 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-17, 19-21, and 84-85 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. It is noted that output of a concrete result (e.g. classification results) to a user, as now recited in claim 1, is considered to be a tangible result.

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However data which is output to a database, an application, or an instrument is not necessarily tangible as the "output" remains within the computer and is never realized in a format which is tangible to one running the method; i.e. the user. As the claims still encompass nonstatutory embodiments, the rejection is maintained.

Response to arguments:

Applicant's arguments filed 8/6/2007 have been fully considered but they are not persuasive.

Applicant alleges independent claim 1, which includes the feature of "acquiring intensity information for a plurality of samples," causes said claim to read on statutory subject matter as the samples are clearly representing tangible objects.

Applicant's allegations are not found persuasive as the feature cited is a method step, which does not necessitate the involvement of tangible objects nor recites a physical transformation as the method step may be performed via a computer alone.

Applicant further alleges that "outputting" the classification is also a tangible feature and specifically "outputting the allelic classification of each of the plurality of samples to at least one of a user, a database, an application, and an instrument" causes said claim 1 to read on statutory subject matter.

Applicant's allegations are not found persuasive as the mere step of "outputting" alone does not cause a claim to be statutory. As set forth above, the claim does recite at least one tangible result; however, the claim also recites

nonstatutory embodiments of outputting. The allegation that "outputting the allelic classification of each of the plurality of samples to at least one of a database, an application, and an instrument" causes said claim to read on statutory subject matter is not persuasive as the option of "outputting" to an application, database or instrument does not necessitate that the result is tangible as the result may never reach an end user or a display. The result in these cases may just be the seed data for another program that also may not produce a tangible result, such as outputting to a display or an end user. Therefore, the non-tangible species of output cause said claim to remain reading on non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following rejection is being maintained:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1-17, 19-21, and 84-85 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 contains the wording "selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele" to describe a discrete combination, which has been deemed as vague and indefinite. It is unclear as to what exactly the wording refers. The method step appears to be identifying a unique allelic classification, wherein the classification comprises a combination of selected

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alleles. However, it is unclear as what alleles may be selected as the only alleles stated in the method steps are a first and a second allele wherein the step clearly states that the selected alleles are "selected from *neither* the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele." Therefore it is unclear as to what alleles are used in the selection process for comprising the discrete combination of alleles that are used for identifying a unique allelic classification. Clearer claim wording is required.

Claims 2-4, 6-17, 19-21, and 84-85 are rejected as being dependent from a rejected claim.

Response to arguments:

Applicant's arguments filed 8/6/2007 have been fully considered but they are not persuasive.

Applicant argues that the meaning of the phrase "selected from neither the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele" is adequately clear and that by its own terms, the phrase enumerates a set of combinations, which define the recited discrete combinations.

Applicant's allegations are not found persuasive as the wording causes confusion as to what alleles are used in the selection process for determining the unique classification as the method step appears to prevent using any of the referenced alleles in the selection process. In other words, it is unclear as what alleles may be selected as the only alleles stated in the method steps are a first

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and a second allele wherein the step clearly states that the selected alleles are "selected from **neither** the first allele nor the second allele, the first allele alone, the second allele alone, and both the first allele and the second allele."

Therefore it is unclear as to what alleles are used in the selection process for comprising the discrete combination of alleles that are used for identifying a unique allelic classification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 5-9, 10-11, and 16, are rejected under 35 U.S.C. 102(e) as being anticipated by Landers et al (US P/N 6,703,228).

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Landers et al. teaches claim 1 at the abstract, col. 25, lines 20-67, col. 3, lines 5-54, col. 6, lines 5-55, col. 26, lines 1-40, col. 30, lines 51-67, col. 31, and col. 32, lines 1-26. The abstract discloses that this invention is a method of genotyping and genomic classification, which represents a method for allelic classification. Landers et al., at cols. 25 and 26, discusses acquiring intensity data from using microarrays from 1,000-10,000s of samples, some of which use several different dyes, which represents acquiring intensity information for a plurality of samples wherein a first intensity is associated with a first allele and a second intensity is associated with a second allele. Landers et al., at col. 3, lines 5-67, discusses using microarray chips containing thousands of samples and using hybridization reactions to acquire intensity information and determine the presence or absence of a particular SNP. It is known to one of ordinary skill in the art that these hybridization reactions for SNP determination involve comparing signal intensities where a particular intensity is associated with a particular allele, which represents a first allele being associated with a first intensity and a second intensity being associated with a second allele. Additionally, Landers et al., at col. 3, discusses determining allele frequencies of an SNP in a population, which represents identifying one or more data clusters that are associated with a discrete allelic combination and are determined, in part, by comparing the first intensity component relative to the second intensity component. Furthermore, Landers et al., at col. 6 discusses generating genomic patterns for individual genomes based on SNP analysis and frequency and hybridization patterns, which enable a classification of the genome to occur,

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which represents evaluating intensity information to identify data clusters and each cluster being associated with a particular allele. Landers et al., at col. 31 and 32, discusses using a likelihood model to predict the probability that a sample will have a particular disease classification or that particular data will be linked, which represents generating a likelihood model that predicts probability that a sample resides within a particular cluster and determines a sample and its associated allelic composition.

Landers et al. teaches claims 5-9 at col. 6, lines 4-58, col. 21, lines 7-22, and col. 23, lines 17-41. Landers et al., at col. 21, teaches a definition for a polymorphic region and discusses three possible genotypes for a diploid organism and how studying SNPs is a good way for genotyping these type of complicated genotypes. Landers et al., at col. 6, discusses generating patterns for SNP alleles in different genomes for genomic classification. In addition, Landers et al., at col. 23, discusses using genotyping to determine phenotypes where homozygous or heterozygous genotypes can contribute to phenotypes, which represents that Landers et al. does genotype different genomes that include homozygous and heterozygous genotypes.

Landers et al. teaches claims 10-11 and 21 at col. 3, lines 25-38. Landers et al. discusses genomic classification based on SNP analysis and the genotyping is done using microarrays.

Landers et al. teaches claim 16 at col. 30, lines 51-67.

Response to arguments:

Applicant's arguments filed 8/6/2007 have been fully considered but they are not persuasive.

Applicant argues that Landers et al. fails to describe any identification action at the level of the alleles themselves and does not teach any technique for separating or identifying the unique allelic combination of a sample determined by detected intensity components.

Applicants allegations are not found persuasive as Landers et al. at the abstract specifically states the invention also relates to methods of preparing the SNP specific oligonucleotides and RCGs, methods of fingerprinting, determining allele frequency for a SNP, characterizing tumors, ***generating a genomic classification code for a genome, identifying previously unknown SNPs,*** and related compositions and kits. Landers et al. clearly teaches an invention drawn to the identification action at the level of the alleles themselves.

Applicant further alleges that Landers et al. fails to describe "evaluating at least the relationship between the first intensity component and the second intensity component for each of the plurality of samples to identify one or more data clusters." Applicant further alleges that Landers et al. entirely fails to describe such an "evaluation" to arrive at the recited "data clusters."

Applicant's allegations are not found persuasive because Landers et al., at cols. 25 and 26, discusses acquiring intensity data from using microarrays from 1,000-10,000s of samples, some of which use several different dyes, which represents acquiring intensity information for a plurality of samples wherein a first intensity is associated with a first allele and a second intensity is associated with

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a second allele. Landers et al., at col. 3, lines 5-67, discusses using microarray chips containing thousands of samples and using hybridization reactions to acquire intensity information and determine the presence or absence of a particular SNP. It is known to one of ordinary skill in the art that these hybridization reactions for SNP determination involve comparing signal intensities where a particular intensity is associated with a particular allele, which represents a first allele being associated with a first intensity and a second intensity being associated with a second allele. Additionally, Landers et al., at col. 3, discusses determining allele frequencies of an SNP in a population, which represents identifying one or more data clusters that are associated with a discrete allelic combination and are determined, in part, by comparing the first intensity component relative to the second intensity component. Furthermore, Landers et al., at col. 6 discusses generating genomic patterns for individual genomes based on SNP analysis and frequency and hybridization patterns, which enable a classification of the genome to occur, which represents evaluating intensity information to identify data clusters and each cluster being associated with a particular allele.

Applicant further alleges that Landers et al. fails to describe the features of "generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within a particular data cluster." Applicant further alleges that Landers et al. fails to contain the further limitation of "applying the likelihood model to the intensity

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information of each of the plurality of samples to identify the associated allelic classification for each corresponding sample.”

Applicant's allegations are not found persuasive as Landers et al., at col. 31 and 32, discusses using a likelihood model to predict the probability that a sample will have a particular disease classification or that particular data will be linked, which represents generating a likelihood model that predicts probability that a sample resides within a particular cluster and determines a sample and its associated allelic composition. Furthermore, Landers et al. at col. 6 specifically states that the invention is drawn to generating a genomic classification code for a genome based on the presence or absence of alleles. The generation of classification codes for genomes reads on generating a likelihood model that predicts the probability that an allelic combination of a selected sample from the plurality of samples will reside within a particular data cluster. Landers et al. generates classification codes for genomes based on allele frequencies from samples, which enables the prediction of a sample that an allelic combination will reside within a particular data cluster of the one or more data clusters, which is based on the intensity information. Therefore, Landers et al. reads on applying the likelihood model to intensity information of each of a plurality of samples.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Marjorie A. Moran/
SPE, AU 1631
11/10/2007